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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,596	06/09/2005	Yoichi Kawazu	2144.0300000/RWE/JKM	4564
28393 7590 10/02/2007 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVE., N.W. WASHINGTON, DC 20005			EXAMINER MEHTA, ASHWIN D	
			ART UNIT 1638	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,596

Applicant(s)

KAWAZU ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 6, 10, 17 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 12-16, 18 and 20 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 11 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 04212005; 06292007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-5, 7-9, 11-16, 18, 20, and 21 in the reply filed on August 13, 2007 is acknowledged. Non-elected claims 6, 10, 17, and 19 are withdrawn from consideration.

Claim Objections

2. Claims 4, 5, and 9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 4 is broadly drawn to a DNA that encodes a sense RNA complementary to the complementary strand of the nucleic acid of claim 2. The specification at page 7 indicates that the term "complementary" is not limited to complete complementarity, as long as the production of Mirafiori lettuce viral (MiLV) proteins can be effectively inhibited. The DNA of claim 4 therefore does not have to be completely complementary to the complementary strand of the nucleic acid of claim 2, which encodes the MiLV coat protein. Claim 4 therefore encompasses DNA that does not encode the MiLV coat protein. Claim 4 can be infringed without infringing claims 1 or 2 and is improperly dependent claim. See MPEP 608.01 (n), part III.

Claim 5 is broadly drawn to a DNA that encodes an antisense RNA complementary to the nucleic acid of claim 2. As this RNA is complementary to that of claim 2, it cannot encode the

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MiLV coat protein. Further, the antisense RNA does not even have to be completely complementary to the nucleic acid of claim 2. Claim 5 can therefore be infringed without infringing claims 1 or 2.

Claim 9 is drawn to a protein encoded by the nucleic acid of claim 1. However, claim 1 only encompasses nucleic acids. Claim 9 can therefore be infringed without infringing claim 1.

3. Claim 11 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

4. Claims 7, 8, and 12 are objected to for depending from a rejected base claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-5 and 9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 is drawn to any nucleic acid that encodes the coat protein of Mirafiori lettuce virus, comprising (a) a nucleic acid that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2; or (b) the nucleic acid of (a) that encodes a coding region of the nucleotide sequence of SEQ ID NO: 1; claims 2 and 3 limit the nucleic acid of claim 1 to being RNA or DNA, respectively; claim 4 is drawn to a DNA that encodes a sense RNA complementary to the

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complementary strand of the nucleic acid of claim 2; claim 5 is drawn to a DNA that encodes an antisense RNA complementary to the nucleic acid of claim 2; claim 9 is drawn to a protein encoded by the nucleic acid of claim 1.

Claims 1-5 and 9 read on nucleic acids and proteins per se which are found in nature and thus, is unpatentable to applicant. The nucleic acid and protein, as claimed, have the same characteristics as those found naturally and therefore do not constitute patentable subject matter. See American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974), American Fruit Growers v. Brodget Co., 283 U.S. 2 (1931), Funk Brothers Seed Co. v. Kalo Inoculant Co., 33 U.S. 127 (1948), Diamond v. Chakrabarty, 206 USPQ 193 (1980). It is suggested that claims 1, 4, 5, and 9 be amended by replacing the article "A" with --An isolated--, to identify a product that is not found in nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 15 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 15: the claim, and claim 20 dependent thereon, is indefinite because it is unclear if the progeny comprises the nucleic acid encoding the MiLV coat protein, the DNA, or the vector. It is suggested that claim 15 be amended by inserting at the end, --wherein the progeny comprises said nucleic acid, said DNA, or said vector.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 4, 5, 9, 12-16, 18, and 20 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A review of claim 4 indicates it is broadly drawn to a large genus: any DNA that encodes a sense RNA complementary to the complementary strand of the nucleic acid of claim 2; claim 5 is broadly drawn to any DNA that encodes an antisense RNA complementary to the nucleic acid of claim 2. Claims 12 and 18 are drawn to a vector comprising the DNA of claim 4 or 5, respectively. Claim 13 is drawn to a transformed plant cell carrying the nucleic acid according to claim 1, the DNA of any one of claims 4-6, or the vector of any one of claims 7, 12, or 18. Claim 14 is drawn to a transformed plant cell comprising the cell of claim 13. Claim 15 is drawn to a progeny or clone of the plant of claim 14. Claim 16 is drawn to propagation material of the plant of claim 14. Claim 20 is drawn to propagation material of the plant of claim 15.

The specification discusses the isolation and determination of the nucleic acid sequence (bases 87-1400 of SEQ ID NO: 1) encoding coat protein (SEQ ID NO: 2) of the Mirafiori lettuce virus (page 13). MiLV is the causative virus of lettuce big-vein disease (page 1). The specification indicates on page 7 that DNAs encoding RNAs that hybridize with RNAs encoding

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MiLV viral proteins, or complementary strands thereof, can be used to suppress the production and function of MiLV viral proteins. The specification also indicates that the term “complementary” is not limited to complete complementarity, as long as the production of MiLV viral proteins can be effectively inhibited (page 7). In order to effectively inhibit expression of a target gene, the antisense and sense RNAs comprise at least 15 nucleotides (paragraph bridging pages 7-8).

However, the specification does not describe a single species of DNA encompassed by claim 4 or 5, other than bases 87-1400 of SEQ ID NO: 1 and the complete complement thereof, that can be used to suppress the production or function of SEQ ID NO: 2, when expressed within a plant cell. The specification does not describe any changes to that can be made to bases 87-1400 of SEQ ID NO: 1, or its complete complement, without altering its ability to suppress the production of SEQ ID NO: 2 when expressed in plant cells. The Federal Circuit provided the appropriate standard for written description in University of California v. Eli Lilly & Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court held that a structural description of a rat cDNA was not an adequate description of broader classes of cDNAs, because a “written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subjected matter sufficient to distinguish it from other materials. Here, the single species of bases 87-1400 of SEQ ID NO: 1, and its complete complement, are not representative of species that differ from it.

Further, the claims encompass DNAs that encode sense RNAs complementary to the complementary strand of claim 2, and DNAs that encode antisense RNAs complementary to the

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nucleic acid of claim 2. Claim 2 encompass any RNA sequence that encodes SEQ ID NO: 2, not just the mRNA sequence encoded by bases 87-1400 of SEQ ID NO: 1. However, antisense- and sense-suppression methods of gene silencing are homology dependent, requiring a high degree of sequence specificity (see for example Baulcombe, Plant Cell, 1996, Vol. 8, pages 1833-1844, particularly pages 1834-1839). The instant specification does not describe a single species of DNA encompassed by the claims that differ from bases 87-1400 of SEQ ID NO: 1, or its complete complement, that would cause RNA-silencing of SEQ ID NO: 1 in plant cells.

Regarding claim 9: bases 87-1400 of SEQ ID NO: 1 encodes the MiLV coat protein of SEQ ID NO: 2. However, claim 9 is not limit to SEQ ID NO: 2, but encompasses any protein encoded by the nucleic acid of claim 1. Because of the potential of alternative reading frames, post-translational modifications, etc., other proteins may be encoded by the nucleic acids encompassed by claim 1. However, the specification only describes SEQ ID NO: 2, which is not representative of other proteins that have different structures and functions. It is suggested that claim 9 be re-written as the following: -- A Mirafiori lettuce virus coat protein having the amino acid sequence set forth in SEQ ID NO: 2.-- Given the breadth of the claims, and the description in the specification, the specification fails to provide written description of the multitude of DNAs encompassed by the claims.

8. Claims 4, 5, 9, 12-16, 18, and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA encoding a sense RNA completely complementary to the completely complementary strand of bases 87-1400 of SEQ ID NO: 1, and an isolated DNA encoding an antisense RNA completely complementary to bases 87-

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1400 of SEQ ID NO: 1, does not reasonably provide enablement for other DNAs encompassed by claims 4 and 5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A review of claim 4 indicates it is broadly drawn to a large genus: any DNA that encodes a sense RNA complementary to the complementary strand of the nucleic acid of claim 2; claim 5 is broadly drawn to any DNA that encodes an antisense RNA complementary to the nucleic acid of claim 2. Claims 12 and 18 are drawn to a vector comprising the DNA of claim 4 or 5, respectively. Claim 13 is drawn to a transformed plant cell carrying the nucleic acid according to claim 1, the DNA of any one of claims 4-6, or the vector of any one of claims 7, 12, or 18. Claim 14 is drawn to a transformed plant cell comprising the cell of claim 13. Claim 15 is drawn to a progeny or clone of the plant of claim 14. Claim 16 is drawn to propagation material of the plant of claim 14. Claim 20 is drawn to propagation material of the plant of claim 15.

Bases 87-1400 of SEQ ID NO: 1 encode the MiLV coat protein (SEQ ID NO: 2), as discussed above. The specification indicates on page 7 that DNAs encoding RNAs that hybridize with RNAs encoding MiLV viral proteins, or complementary strands thereof, can be used to suppress the production and function of MiLV viral proteins. The specification also indicates that the term "complementary" is not limited to complete complementarity, as long as the production of MiLV viral proteins can be effectively inhibited (page 7). In order to effectively inhibit expression of a target gene, the antisense and sense RNAs comprise at least 15 nucleotides (paragraph bridging pages 7-8).

However, the only DNAs encompassed by claims 4 and 5 that are enabled by the specification are bases 87-1400 of SEQ ID NO: 1 itself and its completely complementary sequence. As discussed above, the specification indicates that the term "complementary" is not limited to complete complementarity. Therefore DNAs encompassed by the claims can differ to any extent. However, RNA silencing is sequence homology dependent. Baulcombe et al. teach that antisense- and sense-suppression methods of gene silencing are homology dependent, requiring a high degree of sequence specificity (pages 834-839). Therefore, even sequences differing from SEQ ID NO: 1 by codon degeneracy would not be expected to silence the expression of the MiLV coat protein gene. The specification also teaches that antisense and sense RNAs that inhibit expression of a target gene comprise at least 15 nucleotides. Thomas et al. (Plant J., 2001, Vol. 25, pages 417-425) studied size constraints for PTGS, and determined that the minimum size of an RNA that could cause post-transcriptional gene silencing of its target gene was 23 nucleotides, and having complete identity with the target sequence (page 419). Klahre et al. (PNAS, 2002, Vol. 99, pages 11981-11986) show that a 21-nt sense molecule that has 100% identity to its target sequence, and a 22-nt antisense single-stranded nucleic acid molecule having complete complementarity to its target sequence, could not induce RNA silencing of their target sequences (page 11983). The instant specification does not have any examples showing that DNAs of less than 23 nucleotides, having complete or incomplete complementarity to its target sequence, was able to silence the expression of SEQ ID NO: 1. In the absence of further guidance, undue experimentation would be required by one skilled in the art to use DNAs other than bases 87-1400 of SEQ ID NO: 1, or its complete complement, to silence the expression of the MiLV coat protein.

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Regarding claim 9: bases 87-1400 of SEQ ID NO: 1 encodes the MiLV coat protein of SEQ ID NO: 2. However, claim 9 is not limit to SEQ ID NO: 2, but encompasses any protein encoded by the nucleic acid of claim 1. Because of the potential of alternative reading frames, post-translational modifications, etc., other proteins may be encoded by the nucleic acids encompassed by claim 1. However, the specification does not teach how to use such proteins, or what their function activities are. In the absence of further guidance, undue experimentation would be required for one skilled in the art to determine the functional activities of proteins encompassed by claim 9 that do not have the amino acid sequence of SEQ ID NO: 2, and how to use them. It is suggested that the claim be amended as discussed above. Given the breadth of the claims, unpredictability of the art, and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

9. Claims 1-5, 9, 12-16, 18, and 20 are rejected; claims 7, 8, 11, and 12 are objected; and non-elected claims 6, 10, 17, and 19 are withdrawn from consideration.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and

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September 27, 2007

A handwritten signature in black ink, appearing to read 'Ashwin D. Mehta', is positioned above the printed name.

Ashwin D. Mehta, Ph.D.
Primary Examiner
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